

1. Rejections under 35 U.S.C. § 1112, first paragraph.

Claims 1-8 stand rejected as allegedly lacking adequate written description. Although the Examiner acknowledges that the structural and physical features of Ac and Ds elements are well known in the art, she maintains that structural and physical features of barley plants comprising the elements are not known. Applicants respectfully traverse.

The current invention is based on the Applicants' discovery that the Ac/Ds transposon system can be successfully used in barley to generate a plant with a Ds or Ac element integrated into its genome. Applicants' have produced such barley plants, as shown in the examples. The element integrated into the genome is a physical and structural hallmark of a barley plant of the invention. The plant can be identified based on this hallmark regardless of the location of the element in the genome and the specific phenotype of the plant. For example, an Ac or Ds element in a barley genome can be identified by analyzing genomic DNA, *e.g.*, using hybridization analyses and/or PCR, as exemplified at pages 20 and 21 of the specification.

The written description requirement can be satisfied "by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties" (*see, e.g.*, the MPEP §2163(II)(A)(3)(a)(ii)). Accordingly, the written description requirement has been met. Applicants therefore respectfully request withdrawal of the rejection.

2. Rejections under 35 U.S.C. § 103

Claims 1-14 are rejected as allegedly unpatentable over McElroy *et al.* in view of Wan *et al.* and Bancroft *et al.*; claims 15-16 are rejected as allegedly unpatentable over the same references, further in view of Perera *et al.* Applicants respectfully traverse.

Prior to the Applicants' invention, it could not be determined with a reasonable expectation of success that the Ac/Ds system could be used to generate stable

barley transformants. Indeed, the frequency of Ds transposition varies from species to species (*see, e.g., Izawa et al., p222*). For example, rice, *Arabidopsis*, and tobacco appear to exhibit unique transposition characteristics, described below.

Various factors contribute to the Ds transposition frequency, including the level of expression of the Ac transposase. An Ac transposase integrated into the genome must be expressed at levels sufficient to transactivate Ds element. The level of expression, however, is highly variable. For example, in tobacco it was shown that where Ac transposase was highly expressed, there was an inhibitory rather than a stimulatory effect on transposition frequency. The opposite observation was made with Ac/Ds tagging systems in *Arabidopsis*, where a strong promoter increased the transposition frequency. *See, e.g., Koprek et al., Plant Journal 24:253-263, 2000* (attached hereto as Exhibit A) at page 258, summarizing prior art. Although the art has shown that different promoters can be used to modulate transient expression level in barley (*see, e.g., McElroy et al.*), the effects of Ac and/or Ds copy number can also be important (*see, e.g., summary in Koprek et al., supra, page 258-259*). Furthermore, the Ac/Ds system can also be inactivated in some plants (*see, e.g., Izawa et al.*). Thus, the operation of Ac/Ds in any given plant is variable and consequently, the ability to use the system to generate stable transformants is variable. The rejection does not point to any teaching or principle in the prior art that would indicate that one of skill could expect that barley would successfully support Ac/Ds function such that barley transformants with an Ac or Ds element integrated into the genome could be generated. Thus, the prior art does not render the claimed invention obvious. Applicants therefore request withdrawal of the rejection.

3. Rejections under 35 U.S.C. § 101

Claims 1-8 were rejected as allegedly lacking utility. The rejection alleges that the disclosed use of Ac and Ds transposable elements to transform barley plants generally applies to the use of any type of transposable element to transform any species

Peggy Lemaux, David McElroy and thomas
Koprek
Application No.: 09/384,811
Page 4

of plant, and therefore is not particular to the product claimed. The rejection further alleges that the claimed barley plants are not supported by a substantial asserted utility because no particular phenotypic attributes for any of the claimed plants have been established. Applicants respectfully traverse.

The Examiner fails to meet the burden of establishing that the claimed barley plants lack utility. The application discloses utilities for barley plants generated using the Ac/Ds system. Moreover, the utility of such plants would be readily apparent to one of skill in the art.

The claimed invention is the focus of the assessment of whether an applicant has satisfied the utility requirement (*see, e.g.*, MPEP § 2107.02(I)). As noted above, the current invention provides an Ac/Ds transposon system in barley. The specification discloses a number of utilities for the methods of the invention and the plants produced using the methods. For example, the specification teaches that transgenic barley plants can be generated using the Ac/Ds system *see, e.g.*, page 3, lines 14-25). As appreciated by one of skill in the art, such plants have many different uses. For example, barley plants that express a beneficial transgene, but do not contain the resistance or screenable markers used in the transformation vector can be generated (*see, e.g.*, page 4, lines 20-23). Barley plants with tagged genes and stable insertion mutations can also be obtained (*see, e.g.*, page 4, lines 27-28). These plants can be used, for example, as a library for the isolation of barley genes (*see, e.g.*, page 13, lines, 15-24). Each of these utilities is specific, substantial, and credible.

The utilities are substantial because they are a "real world" use (*see, e.g.*, the MPEP at §2107.01(I)). The utilities are specific because they apply to the invention as claimed, *i.e.*, a barley plant comprising a Ds or Ac element integrated into the genome, not all barley plants. The utilities are credible because they are believable to a person of ordinary skill in the art.

The Examiner appears to believe that because the utility of plants generated using a transposon system such as an Ac/Ds system is known to one of skill in

the art, the utility cannot be applied to barley plants. Applicants respectfully disagree. The rejection fails to set forth reasoning or evidence supporting this contention. Indeed, it would appear that the utility is a well-established utility. Accordingly, a rejection based on lack of utility, should not be imposed (*see, e.g.*, MPEP §2107(II.)(A)).

In view of these remarks, Applicants respectfully request withdrawal of the rejection.

4. Rejections under 35 U.S.C. § 112, first paragraph-utility

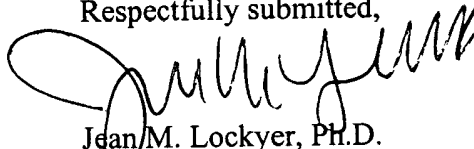
Claims 1-8 were also rejected under 35 U.S.C., first paragraph. The rejection alleges that one of skill in the art would not know how to use the claimed barley plants. Applicants respectfully traverse. The application meets the utility requirements for the reasons set forth above. Applicants therefore respectfully request withdrawal of the rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Jean M. Lockyer, Ph.D.
Reg. No. 44,879

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
JML
SF 1323705 v1